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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,904	07/23/2001	Spencer B. Farr	400742000200	4189

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EXAMINER	
GOLDBERG, JEANINE ANNE	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/911,904	Applicant(s) FARR ET AL.	
	Examiner Jeanine A Goldberg	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/19/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 12-20, drawn to methods of identifying a toxicologically relevant canine gene by obtaining gene expression patterns with treated and untreated canine cells and comparing the patterns; methods for determining a toxicological response by exposing cells to an agent and obtaining a gene expression profile which is compared to a gene expression profile of toxicologically relevant canine genes; methods for screening an agent for potential toxicological response by exposing cells to an agent and comparing the response to a profile, classified in class 435, subclass 6.

II. Claims 9-11, drawn to methods of isolating canine genes indicative of a toxicological response to an agent by using primers from non-canine genes to amplify canine genes, classified in class 435, subclass 91.2.

III. Claims 21-23, drawn to a method for generating a canine array by isolating at least ten canine genes and attaching said genes to a substrate, classified in class 435, subclass 174.

IV. Claims 24-39, drawn to an array of at least 10 canine genes and an array comprising at least 10 genes of Table 8 or 9, classified in class 435,

subclass 287.1 and 536/23.1, for example. (Subject to a further restriction requirement below)

V. Claim 40, drawn to a method for obtaining a gene expression profile by exposing population of cells to an agent, obtaining cDNA from said population, labeling said cDNA and containing said cDNA with an array, classified in class 435, subclass 287.2.

2. The inventions are distinct, each from the other because of the following reasons:

A) The inventions of Group I, II, III and V are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group I is for methods of identifying a toxicologically relevant canine gene by obtaining gene expression patterns with treated and untreated canine cells and comparing the patterns. Alternatively, the method of Group II is for methods of isolating canine genes indicative of a toxicological response to an agent by using primers from non-canine genes to amplify canine genes. The method of Group III is a method for generating a canine array by isolating at least ten canine genes and attaching said genes to a substrate. An the method of Group V is a method for obtaining a gene expression profile by exposing population of cells to an agent, obtaining cDNA from said population, labeling said cDNA and containing said cDNA with an array. The method of Group II uses primers, whereas the other groups do not rely upon primers. The method of Group III is for making an array, whereas the methods of Group I, II do not rely upon an array. The method of Group IV required

obtaining cDNA and labeling the cDNA which is not required by any of the other methods. Therefore the methods are distinct over one another.

B) Inventions IV and (V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the array comprising canine toxicological gene may be used in methods aside from gene expression profiles. For example, the array may be used in isolation, purification or other screening assays.

C) Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the array may be made in a materially different manner such as spotting or mask layers. Moreover the method of Claim 21 requires gene are attached to the substrate, whereas the array comprises portions of genes. Therefore, the product may be made in a materially different means because the method of making the array does not encompass making the full scope of the product claims.

Further Sequence Restriction Requirement:

3. Claims 24-29 are drawn in part the arrays containing at least 10 nucleic acid canine genes. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Applicants must further elect a single nucleic acid sequence or single combination of 10 nucleic acid sequences (See MPEP 803.04). Either the claims may be read to require a single nucleic acid (i.e. an array comprising at least 10 nucleic acids wherein one of the at least 10 nucleic acid molecules is SEQ ID NO: 1) OR applicant's may select a single combination of nucleic acids (wherein the 10 nucleic acid molecules are SEQ ID NO: 1-10).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Applicant is required to select one of the individual sequences for examination. The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Should applicant traverse on the ground that the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Pauline Farrier, whose telephone number is (703) 305-3550.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg
Jeanine Goldberg
August 30, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600